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INFECTION CONTROL

LETTERS TO THE EDITOR

To the Editor:

The new and forthcoming *Guidelines for the Prevention and Control of Nosocomial Infections* by CDC raises a legal issue which should be clarified. In his introduction to the Guidelines, Dr. Haley indicates that the Guidelines "are not intended to have the force of law or regulation." The editorial by Dr. McGowan, however, observes that the Guidelines may nevertheless constitute a "national standard" with which hospitals may feel obliged to comply.

As an attorney specializing in the litigation of cases involving medical and hospital negligence, I can confirm Dr. McGowan's belief. Despite the intention of CDC, I have no doubt that the Guidelines would be used at trial in order to establish the applicable standard of care. It is difficult to believe that a jury would not find a departure from these Guidelines (except for Category II recommendations) to be a departure from reasonable care.

By way of analogy, courts have held that failure to comply with JCAH standards is evidence of nonconformity with a national standard of care. Given the great weight of authority which went into the compiling and outside review of these guidelines, it seems clear that they will receive a similar imprimatur.

Presumably the Guidelines are being issued with the hope that hospitals will follow them. Although CDC does not intend to and cannot give them the force of law, they will nevertheless have the same ultimate effect.

Stephen H. Mackauf
Gair, Gair & Conason
Counselors at Law
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This letter was referred to Dr. Robert Haley, who wrote the following reply:

The intent of the CDC Guidelines for the Prevention and Control of Noscomial Infections was stated clearly in the Introduction [Infect Control 1981: 2(2):123-4] and we see no need for further elaboration in response to Mr. Mackauf's comments.

Robert W. Haley, M.D.
Director
Hospital Infections Program
Center for Infectious Diseases
Centers for Disease Control
Atlanta, GA 30333

To the Editor:

I am the Infection Control Nurse in a 70 bed rural hospital. Our physicians are all general practitioners except for two board [certified] surgeons. We have an average of 300 babies born each year.

In our obstetrical department we are presently using Betadine solution for perineal care and before performing any vaginal examinations. Some of the nurses have complained that because of the color, it is difficult to differentiate between the Betadine and meconium stool. Would you please tell me what is being used in the other areas of the country? Has this problem been reported by other nurses? Is there some other solution being used? Could you suggest an alternative?

I would appreciate any advice or suggestions that you might offer, and I do thank you sincerely for your help.

Novice G. Richards, R.N., I.C.N.
Morenci Hospital
Morenci, Arizona 85540

This letter was referred to William Ledger, who wrote the following reply.

This is an interesting question, and it does pose a dilemma. How do you use an effective antibacterial solution whose color may diminish the ability to recognize a clinical problem? We do use an iodine solution in the care of patients in labor. I believe it is the most effective antibacterial solution available, and this is the reason for our selecting it. Although it may be more difficult to recognize meconium, this has not been a problem for us. Another potential difficulty is the absorption of iodine through the vagina, with elevated levels reported in both the mother and the fetus. I would be very concerned if this continued throughout pregnancy, but I don't know of any bad effects from this short-term utilization.

William J. Ledger, M.D.
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Important News from Searle

In clinical trials with Flagyl I.V.™ (metronidazole HCl), the frequency and type of adverse reactions followed the pattern of 17 years' previous experience with oral metronidazole.

Flagyl I.V. is effective and relatively safe.

- No cases of pseudomembranous colitis have been reported to date with Flagyl I.V.
- No cases of aplastic anemia have been reported.
- Although phlebitis has been reported, this reaction can be avoided or minimized by proper I.V.-admixture and -administration procedures.
- Metronidazole has been shown to be carcinogenic in mice and rats. The relevance of this finding with regard to humans has not been demonstrated. See prescribing information for *Warnings* and *Indications.*

Drug-induced resistance to Flagyl I.V.™ (metronidazole HCl) has not been documented, and the development of significant resistance appears unlikely to occur.

- Although specific anaerobes may be naturally resistant to metronidazole, drug-induced resistance has not been documented.
- No drug-induced resistance was reported in Flagyl I.V. clinical trials.
- Oral metronidazole usage (for trichomoniasis and amebiasis), in over 20 million patients and for more than 17 years in the United States alone, has not resulted in the reported development of drug resistance in anaerobic bacteria.
- Drug-induced resistance appears unlikely to occur because of the mechanism of action of Flagyl I.V.

Please see brief summary of prescribing information on next page of this advertisement.

FLAGYL I.V.™ (metronidazole HCl)

Flagyl I.V.™
(metronidazole HCl)

WARNING

Metronidazole has been shown to be carcinogenic in mice and rats (see *Warnings*). Its use, therefore, should be reserved for serious anaerobic infections where, in the judgment of the physician, the benefit outweighs the possible risk.

Indications and Usage: Flagyl I.V. is indicated in the treatment of serious infections caused by susceptible anaerobic bacteria. Indicated surgical procedures should be performed in conjunction with Flagyl I.V. therapy. In a mixed aerobic and anaerobic infection, antibiotics appropriate for the treatment of the aerobic infection should be used in addition to Flagyl I.V.

Flagyl I.V. has been found to be effective in *Bacteroides fragilis* infections resistant to clindamycin, chloramphenicol, and penicillin.

INTRA-ABDOMINAL INFECTIONS, including peritonitis, intra-abdominal abscess and liver abscess, caused by *Bacteroides* species including the *B. fragilis* group (*B. fragilis, B. distasonis, B. ovatus, B. thetaiotaomicron, B. vulgatus*), *Clostridium* species, *Eubacterium* species, *Peptococcus* species, and *Peptostreptococcus* species.

SKIN AND SKIN STRUCTURE INFECTIONS caused by *Bacteroides* species including the *B. fragilis* group, *Clostridium* species, *Peptococcus* species, *Peptostreptococcus* species, and *Fusobacterium* species.

GYNECOLOGIC INFECTIONS, including endometritis, endomyometritis, tubo-ovarian abscess, and post-surgical vaginal cuff infection, caused by *Bacteroides* species including the *B. fragilis* group, *Clostridium* species, *Peptococcus* species, and *Peptostreptococcus* species.

BACTERIAL SEPTICEMIA caused by *Bacteroides* species including the *B. fragilis* group, and *Clostridium* species.

The following conditions when caused by *Bacteroides* species including the *B. fragilis* group:

BONE AND JOINT INFECTIONS, as adjunctive therapy

CNS INFECTIONS, including meningitis and brain abscess

LOWER RESPIRATORY TRACT INFECTIONS, including pneumonia, empyema, and lung abscess

ENDOCARDITIS

Contraindications: Prior history of hypersensitivity to metronidazole or other nitroimidazole derivatives.

Warnings: Convulsive seizures and peripheral neuropathy have been reported in patients treated with metronidazole. The appearance of abnormal neurologic signs demands the prompt evaluation of the continuation of the drug.

Metronidazole has shown evidence of carcinogenicity in studies involving chronic, oral administration in mice and rats, but similar studies in hamsters were negative. It has also shown mutagenicity in some *in vitro* assays, but *in vivo* studies did not show a potential for genetic damage.

Precautions: Since patients with severe hepatic disease metabolize metronidazole slowly with resultant accumulation of metronidazole and its metabolites in the plasma, doses below those usually recommended should be administered cautiously. Known or previously unrecognized candidiasis may present more prominent symptoms during therapy and requires treatment with a candicidal agent.

Use with care in patients with evidence of or history of blood dyscrasia. Mild leukopenia has been observed during metronidazole administration; however, no persistent hematologic abnormalities attributable to metronidazole have been observed in clinical studies. Total and differential leukocyte counts are recommended before and after therapy.

Metronidazole has been reported to potentiate the anticoagulant effect of warfarin and other oral coumarin anticoagulants resulting in a prolongation of prothrombin time and this should be considered when Flagyl I.V. is prescribed for patients on such anticoagulant therapy.

Avoid alcoholic beverages during metronidazole therapy.

Metronidazole may interfere with certain chemical analyses for serum glutamic oxalacetic transaminase resulting in decreased values.

Safe use in pregnancy has not been established. Metronidazole crosses the placental barrier and enters the fetal circulation rapidly. This drug should be used during pregnancy only if clearly needed.

Metronidazole is secreted in breast milk in concentrations similar to those found in plasma. If use of Flagyl I.V. is deemed essential, an alternative method of infant feeding should be used.

Safety and effectiveness in children have not been established.

Adverse Reactions: Convulsive seizures, nausea, vomiting, abdominal discomfort, diarrhea, unpleasant metallic taste, reversible neutropenia (leukopenia), erythematous rash, pruritus, headache, dizziness, syncope, fever, darkened urine, and thrombophlebitis after intravenous infusion that can be minimized or avoided by not prolonging use of indwelling intravenous catheters. Since persistent peripheral neuropathy has been reported in some patients receiving prolonged metronidazole therapy, patients should be observed carefully if neurologic symptoms occur and a prompt evaluation made of the benefit/risk ratio of the continuation of therapy.

Additional adverse reactions have been reported during treatment with oral metronidazole: anorexia, epigastric distress, constipation; furry tongue, glossitis, and stomatitis sometimes with a sudden overgrowth of *Candida*; flattening of the T-wave in electrocardiographic tracings; vertigo, incoordination, ataxia, confusion, irritability, depression, weakness, insomnia, urticaria, flushing, nasal congestion, dryness of mouth (or vagina or vulva), dysuria, cystitis, polyuria, incontinence, a sense of pelvic pressure, proliferation of *Candida* in the vagina, dyspareunia, decrease of libido, proctitis, and fleeting joint pains.

Dosage and Administration:

Adults:

Loading Dose—15 mg/kg infused over one hour (approximately 1 g for a 70-kg adult).

Maintenance Dose—7.5 mg/kg infused over one hour every six hours (approximately 500 mg for a 70-kg adult). The first maintenance dose should be instituted six hours following the initial loading dose.

Parenteral therapy may be changed to oral Flagyl® (metronidazole) when conditions warrant, based upon the severity of the disease and the response of the patient to Flagyl I.V. treatment. The usual adult oral dosage is 7.5 mg/kg every six hours. A maximum of 4.0 g should not be exceeded during a 24-hour period.

Patients with severe hepatic disease metabolize metronidazole slowly, with resultant accumulation of metronidazole and its metabolites in the plasma. Accordingly, for such patients, doses below those usually recommended should be administered cautiously. Close monitoring of plasma metronidazole levels and toxicity is recommended.

The dose of Flagyl I.V. should not be specifically reduced in anuric patients since accumulated metabolites may be rapidly removed by dialysis.

The usual duration of therapy is 7 to 10 days; however, infections of the bone and joint, lower respiratory tract, and endocardium may require longer treatment.

Flagyl I.V. is to be administered by slow intravenous drip infusion only, either as a continuous or intermittent infusion. I.V. admixtures containing Flagyl I.V. and other drugs should be avoided. If used with a primary intravenous fluid system, the primary solution should be discontinued during infusion. Flagyl I.V. cannot be given by direct intravenous injection (I.V. bolus) because of the low pH (0.5 to 2.0) of the reconstituted product. FLAGYL I.V. MUST BE FURTHER DILUTED AND NEUTRALIZED FOR I.V. INFUSION.

How Supplied: Flagyl I.V. (metronidazole HCl) is supplied in single-dose lyophilized vials each containing 500 mg metronidazole equivalent, and 415 mg mannitol.

Searle Pharmaceuticals Inc.
Box 5110, Chicago, Illinois 60680

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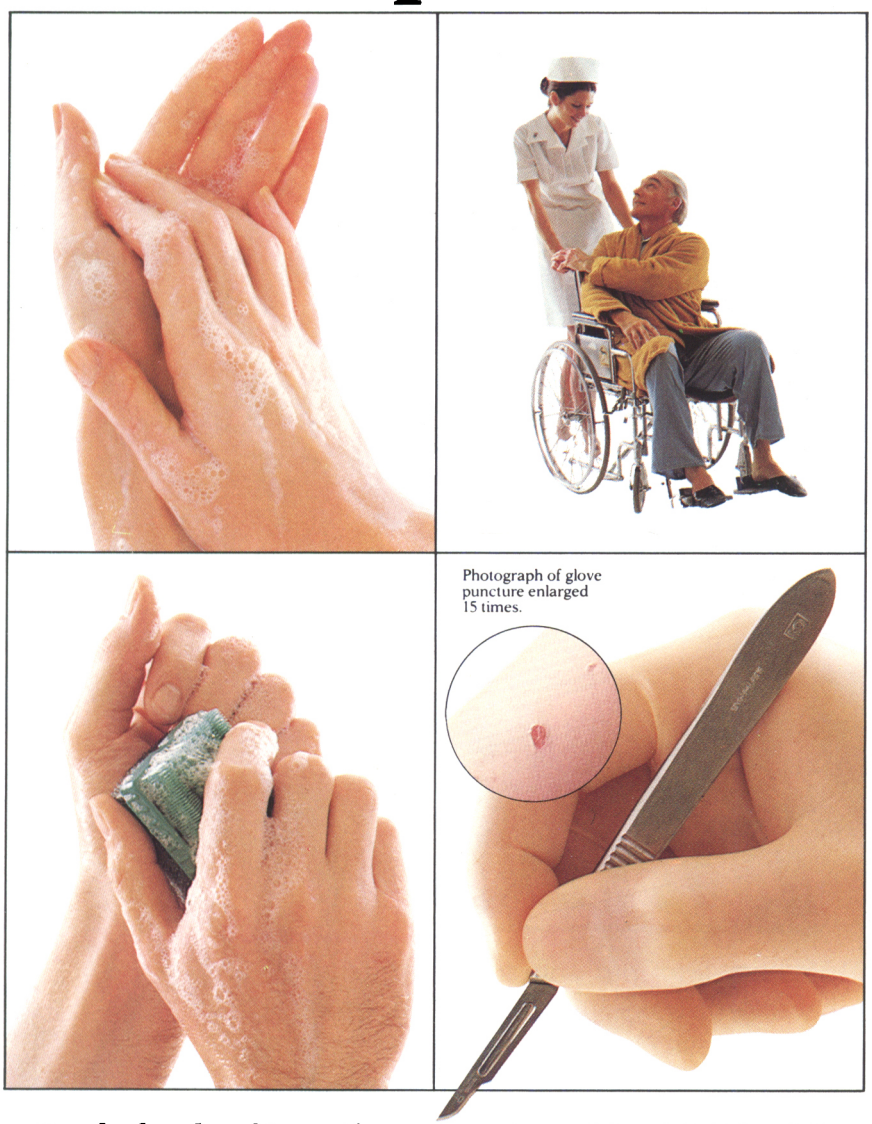
SEARLE

In patient contact and in the OR: Staff care ...not staph carriers.



Regular handwashing with pHisoHex reduces skin levels of gram-positive bacteria—especially staph, a major cause of hospital infection.[1] It helps to prevent transmission of gram-positive infections by personal contact. After regular use, an antibacterial film develops that provides sustained protection.

In the OR, pHisoHex retards bacterial regrowth inside the glove, providing extended protection in longer procedures and in cases of glove puncture.[2]

A gentle emulsion (pH 5.0 to 6.0), pHisoHex minimizes drying and cracking that invite bacterial colonization.

pHisoHex®
brand of
hexachlorophene detergent cleanser

contains a colloidal dispersion of hexachlorophene 3% (w/w) in a stable emulsion consisting of entsufon sodium, petrolatum, lanolin cholesterols, methylcellulose, polyethylene glycol, polyethylene glycol monostearate, lauryl myristyl diethanolamide, sodium benzoate, and water. pH is adjusted with hydrochloric acid. Entsufon sodium is a synthetic detergent (sodium octylphenoxyethoxyethyl ether sulfonate).

Before prescribing, please consult the following product information:

CLINICAL PHARMACOLOGY: pHisoHex is a bacteriostatic cleansing agent. It cleanses the skin thoroughly and has bacteriostatic action against staphylococci and other gram-positive bacteria. Cumulative antibacterial action develops with repeated use. This antibacterial residue is resistant to removal by many solvents, soaps, and detergents for several days.

pHisoHex has the same slight acidity as normal skin (pH value 5.0 to 6.0).

INDICATIONS AND USAGE: pHisoHex is indicated for use as a surgical scrub and a bacteriostatic skin cleanser. It may also be used to control an outbreak of gram-positive infection where other infection control procedures have been unsuccessful. Use only as long as necessary for infection control.

CONTRAINDICATIONS: pHisoHex should not be used on burned or denuded skin.

It should not be used as an occlusive dressing, wet pack, or lotion.

It should not be used routinely for prophylactic total body bathing.

It should not be used as a vaginal pack or tampon, or on any mucous membranes.

pHisoHex should not be used on persons with sensitivity to any of its components. It should not be used on persons who have demonstrated primary light sensitivity to halogenated phenol derivatives because of the possibility of cross-sensitivity to hexachlorophene.

WARNINGS: RINSE THOROUGHLY AFTER USE, especially from sensitive areas such as the scrotum and perineum.

Rapid absorption of hexachlorophene may occur with resultant toxic blood levels, when preparations containing hexachlorophene are applied to skin lesions such as ichthyosis congenita, the dermatitis of Letterer-Siwe's syndrome, or other generalized dermatological conditions. Application to burns has also produced neurotoxicity and death.

pHisoHex SHOULD BE DISCONTINUED PROMPTLY IF SIGNS OR SYMPTOMS OF CEREBRAL IRRITABILITY OCCUR.

Infants, especially premature infants or those with dermatoses, are particularly susceptible to hexachlorophene absorption. Systemic toxicity may be manifested by signs of stimulation (irritation) of the central nervous system, sometimes with convulsions.

Infants have developed dermatitis, irritability, generalized clonic muscular contractions and decerebrate rigidity following application of a 6 per cent hexachlorophene powder. Examination of brainstems of those infants revealed vacuolization like that which can be produced in newborn experimental animals following repeated topical application of 3 per cent hexachlorophene. Moreover, a study of histologic sections of premature infants who died of unrelated causes has shown a positive correlation between hexachlorophene baths and lesions in white matter of brains.

pHisoHex is intended for **external use only.** If swallowed, pHisoHex is harmful, especially to infants and children. **pHisoHex should not be poured into measuring cups, medicine bottles, or similar containers since it may be mistaken for baby formula or other medications.**

PRECAUTION: pHisoHex suds that get into the eyes accidentally during washing should be rinsed out promptly and thoroughly with water.

ADVERSE REACTIONS: Adverse reactions to pHisoHex may include dermatitis and photosensitivity. Sensitivity to hexachlorophene is rare; however, persons who have developed photoallergy to similar compounds also may become sensitive to hexachlorophene.

In persons with highly sensitive skin, the use of pHisoHex may at times produce a reaction characterized by redness and/or mild scaling or dryness, especially when it is combined with such mechanical factors as excessive rubbing or exposure to heat or cold.

TREATMENT OF ACCIDENTAL INGESTION: The accidental ingestion of pHisoHex in amounts from 1 to 4 oz has caused anorexia, vomiting, abdominal cramps, diarrhea, dehydration, convulsions, hypotension and shock, and in several reported instances, fatalities.

If patients are seen early, the stomach should be evacuated by emesis or gastric lavage. Olive oil or vegetable oil (60 ml or 2 fl oz) may then be given to delay absorption of hexachlorophene, followed by a saline cathartic to hasten removal. Treatment is symptomatic and supportive; intravenous fluids (5% dextrose in physiologic saline solution) may be given for dehydration. Any other electrolyte derangement should be corrected. If marked hypotension occurs, vasopressor therapy is indicated. Use of opiates may be considered if gastrointestinal symptoms (cramping, diarrhea) are severe. Scheduled medical or surgical procedures should be postponed until the patient's condition has been evaluated and stabilized.

HOW SUPPLIED: pHisoHex is available in unbreakable plastic squeeze bottles of 5 oz (refillable) and 1 pt, and in plastic bottles of 1 gal.

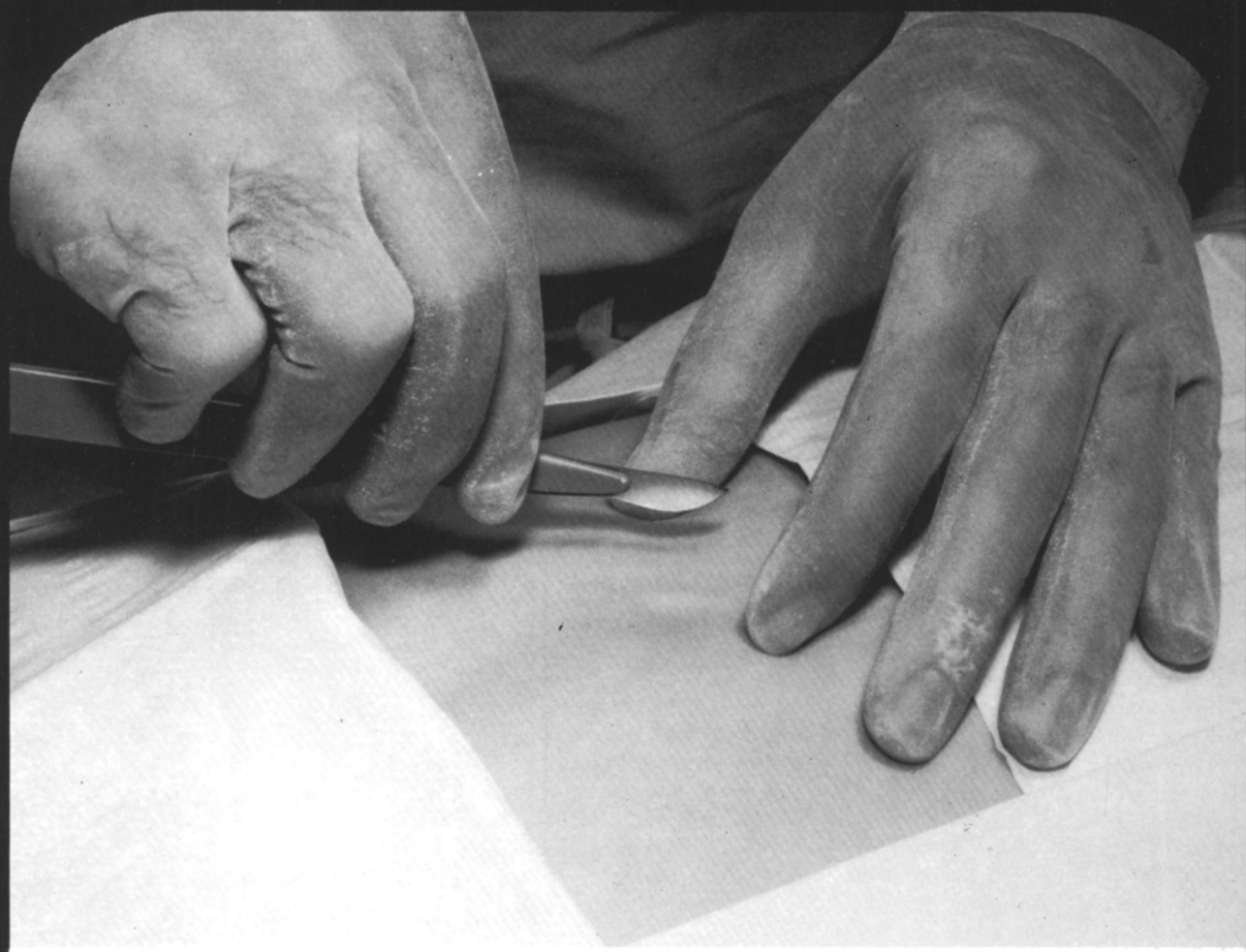
Also available—¼ oz (8 ml) unit packets, boxes of 50.

pHisoHex should not be dispensed from, or stored in, containers with ordinary metal parts. A special type of stainless steel must be used or undesirable discoloration of the product or oxidation of metal may occur. Specially designed dispensers for hospital or office use may be obtained through your local dealer.

References: 1. Steere AC, Mallison GF: Handwashing practices for the prevention of nosocomial infections. *Ann Intern Med* 83:683-690, 1975. **2.** Data on file, Winthrop Laboratories.

3306

Winthrop Laboratories
New York, NY 10016



You need to know now!

Delayed results from culture tests are fine, but you also need Diack® and Vac controls to tell you instantly if something has gone wrong during sterilization. No waiting. No guessing. No worrying. As soon as you open that pack, a glance tells you if something is wrong. It may be a human error or a sterilizer malfunction . . . but Diack is there to tell you on the spot. Reliably. Simply. If the glass-enclosed pellet hasn't melted, something is definitely wrong. Diacks: 250° F. Vacs: 270° F. Simply reliable . . . reliably simple.

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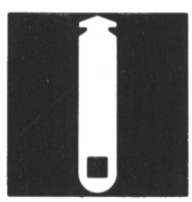

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